

WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.**

The medicine may be authorised for additional or different uses by national medicines regulatory authorities.

* https://extranet.who.int/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[MA195 trade name][†]

Artesunate + sodium bicarbonate + sodium chloride

If you are a carer or parent looking after the person who takes this medicine, use this leaflet to give the medicine correctly and take note of the warnings and side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have questions about the medicine, ask your health care provider.
- This medicine is for you only. Do not pass it on to others. It may harm them, even if their illness seems to be the same as yours.
- If you get any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [MA195 trade name] is and what it is used for
2. What you need to know before you take [MA195 trade name]
3. How to take [MA195 trade name]
4. Possible side effects
5. How to store [MA195 trade name]
6. Contents of the pack and other information

1. What [MA195 trade name] is and what it is used for

[MA195 trade name] is a medicine used to treat severe malaria in adults and children. It contains the active substance artesunate and is made up into a solution that is given by injection.

Malaria is caused by infection with a parasite called *Plasmodium*, spread by the bite of an infected mosquito. [MA195 trade name] is used only when the infection is severe enough that it cannot be treated with medicines by mouth.

Your health care provider will follow the most recent official guidelines on the use of malaria medicines to select the right medicine for your malaria treatment.

2. What you need to know before you are given [MA195 trade name]

[MA195 trade name] should **not be used** if you are allergic to the active substance or any of the other ingredients of this product (see section 6).

Warnings and precautions

After you have been treated with [MA195 trade name] to bring down the most severe symptoms of your malaria infection, you will need to take malaria medicines by mouth to complete the treatment.

Some people treated with this medicine have developed increased breakdown of red blood cells in the body after treatment has finished, leading to low red blood cell levels within the first month after therapy. This has been seen most often in small children and travelers. Your health care provider may carry out blood tests to check for this for the first few weeks after treatment.

[†]Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

Taking other medicines

Please inform the health care provider if the patient is taking or has recently taken any other medicines, including medicines bought without prescription.

Pregnancy and breast-feeding

Pregnancy

Severe malaria is especially dangerous during pregnancy, so if you need treatment with [MA195 trade name] it will be given to you. Use during pregnancy is not expected to cause harm to you or the unborn baby.

Breast-feeding

A small amount of the medicine enters human breast milk, but if you are well enough to breast-feed this is not expected to cause any problems for your baby. However, there is not enough medicine to protect the child from malaria.

Driving and using machines

[MA195 trade name] is not likely to affect your ability to drive or operate machinery.

However, make sure you feel well enough to take on any skilled tasks.

3. How [MA195 trade name] is given

Artesunate is given by injection into a vein or into a muscle (usually the muscle of your thigh). The dose is based on your weight. Your health care provider will work out the right dose to give.

Treatment is given for at least a day, until you are well enough to be treated by malaria medicines taken by mouth.

If you have any further questions on the use of this product, ask your health care provider.

4. Possible side effects

Like all medicines, [MA195 trade name] can cause side effects, but not everybody gets them. Some of these may be difficult to detect, and may be similar to effects of the disease itself.

Very common side effects (may affect more than 1 in 10 people)

Low red blood cell counts (anaemia), changes in levels of blood cells called reticulocytes, damage to red blood cells that may happen up to one month after treatment has finished, especially in young children and visitors from areas without malaria

Common side effects (may affect up to 1 in 10 people):

Dizziness, altered ability to taste, headache, slow heart rate (bradycardia), low blood pressure, cough, runny nose, vomiting, pain in the belly (abdomen), cramps, diarrhoea increased levels of liver enzymes and a substance called bilirubin seen in blood tests, yellowing of the skin or eyes (jaundice), blood pigment in urine, reduced kidney function, joint and muscle pain, fever.

Uncommon side effects (may affect up to 1 in 100 people):

Loss of appetite, flushing, nausea (feeling sick), constipation, severe painful rashes with flu-like symptoms (Stevens-Johnson syndrome), itching, rashes, tiredness, pain at the injection site.

Not known (frequency cannot be estimated from the available data):

Breakdown of blood cells (immune haemolytic anaemia), altered electrical activity in the heart (QT prolongation), severe allergic reaction (anaphylaxis).

Anaemia (low red blood cells) may occur within one month after treatment. It has been reported especially in young children and in travelers. If you feel excessively tired, weak or short of breath up to 4 weeks after treatment, inform your health care provider.

Reporting of side effects

If you get a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

5. How to store [MA195 trade name]

Store below 30°C. Do not refrigerate or freeze. Avoid excursions above 30°C.

Keep the vial and ampoule in the provided carton to protect from light.

Keep this medicine out of the sight and reach of children.

This medicine must not be used after the expiry date stated on the label after 'EXP'.

This medicine must not be used if there is description of the visible signs of deterioration or that it is different from the description below.

Do not throw away any medicines in wastewater or household waste. Ask your health care provider how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What [MA195 trade name] contains

- The active ingredient is artesunate. No other excipients.
- The solvent for reconstitution contains arginine, sodium bicarbonate, phosphoric acid and water for injection.

There is too little sodium in this medicine to have any effect, even if you are on a low-sodium diet.

What [MA195 trade name] looks like and contents of the pack

Artesunate powder for injection is packed in a clear colourless type I glass vial (10 mL) with a type I grey halogenated butyl rubber stopper, crimped with a purple aluminium-plastic cap

The solvent for reconstitution (arginine and sodium bicarbonate) is packed in a clear colourless type I glass ampoule (9 mL).

Pack size: [MA195 trade name] is supplied in a carton that contains one vial of artesunate powder for injection and one ampoule of the solvent (arginine and sodium bicarbonate) that are placed in a plastic (PVC) tray.

Supplier and Manufacturer

Supplier

Guilin Pharmaceutical Co., Ltd
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For any information about this medicine, contact the local representative of the supplier:

This leaflet was last revised in January 2025

Detailed information on this medicine is available on the World Health Organization (WHO) website:
<https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products>

This information is intended for health care providers only:

Instructions for reconstitution

When reconstituted correctly, one vial of [MA195 trade name] will yield 9 mL of a solution for intravenous or intramuscular administration (20 mg/mL).

For patients weighing over 75 kg, more than 1 vial of [MA195 trade name] will be needed for each dose. The required number of product packs should be determined as follows.

Patient weight	Number of vials of artesunate (180 mg) needed
up to 75 kg	1
76 to 100 kg	2

- Using a syringe, withdraw 9 mL of the supplied sodium bicarbonate and arginine solvent from the ampoule and inject into the vial containing the artesunate powder. The product must be prepared with the supplied solvent.
- Gently shake the vial for as long as necessary until the powder is completely dissolved and the solution is clear. This may take several minutes. If the solution appears cloudy or a precipitate is present, it should be discarded.
- The reconstituted solution will contain 20 mg artesunate per mL of solvent, for intravenous or intramuscular use.

Once reconstituted, the artesunate solution must be used within one hour. Discard any unused solution.